

Please cancel claims 19 and 20.

### REMARKS

#### The Present Invention

The present invention is directed to a composition consisting essentially of a fibrate dissolved in at least one structured lipid.

#### The Office Action

The Office Action made the following rejections:

- 1) Claims 1, 3-5, 12, 14-17 and 19-20 were rejected under 35 U.S.C. § 102(b) as being anticipated by Lacy (U.S. Patent No. 5,645,856); and
- 2) Claims 1, 3-5, 12, 14-17 and 19-20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lacy alone or in combination with Sanchez (U.S. Patent No. 5,494,936).

#### Claim Amendments

Applicants have amended claim 1 to provide that the compositions consist essentially of a fibrate dissolved in at least one structured lipid and have canceled claims 19 and 20 thereby excluding the presence of co-solvents.

Discussion of 35 U.S.C. Sec. 102(b), Rejection Over Lacy

The Examiner has rejected claims 1, 3-5, 12, 14-17 and 19-20 under 35 U.S.C. §102(b) as being anticipated by Lacy. In making this rejection, the Examiner stated, "Applicant, while acknowledging that Lacy discloses caprylic/capric triglycerides (medium chain esters), argues that these materials are not structured lipids, which are lipids containing saturated medium and long chain fatty acids esterified on the same glycerol molecule. This argument is very confusing because Lacy teaches the same triglycerides. . .". It should be noted that Lacy teaches triglyceride oils that contain saturated C6 - C12 fatty acids. An example of such an oil is fractionated vegetable oils, e.g., fractionated coconut oils. Specific examples of capric and/or caprylic triglycerides include Miglyol 810, Miglyol 812, Neobee M5, Captex 300, and Captex 355 (column 9, lines 20-28). The present invention teaches structured lipids, which are NOT capric and/or caprylic triglycerides. The uniqueness of an exemplary structured lipid is described in U.S. Patent No. 4,952,606, attached hereto as Exhibit A. The patent describes the nutritional benefits of structured lipids in column 1, lines 43-50 and further describes the physical and chemical differences of these lipids when compared to medium chain triglycerides (C6 - C12, essentially C8 - C10) in Example 1.

In addition, the nutritional and physical and chemical differences between structured lipids and medium chain triglycerides are described more completely in the following two (2) published articles: (1.) Structured Lipids: An Alternative Energy Source, Nutrition in Clinical Practice (NCP), Vol 10, No. 3, June 1995, Pages 89-90 (an editorial), and (2.) Metabolic Effects of Structured

Triglycerides in Humans, Nutrition in Clinical Practice (NCP), Vol. 10, No. 3, June 1995, pages 91-97 (a review article). These articles are attached hereto as Exhibits B and C.

To date, structured lipids have been considered for their nutritional value, but the lipids have not been considered as a drug delivery system for the oral delivery of pharmaceuticals. Lacy does not teach nor anticipate the general class of custom or designer molecules known as structured lipids.

The Examiner also stated, "Even assuming that Lacy does not teach saturated lipids, the Examiner points out that page 3, lines 34-39 do not provide a specific definition of the term 'structured lipids.' For instance, at this site, applicant recites expressions such as 'Representative structured lipids include, but are not limited to, ---', '--- and in general, include those lipids containing saturated medium and long chain fatty acids---.'"

The present invention defines structured lipids on page 3, lines 34-39 as, "Representative structured lipids include, but are not limited to, caprylic/capric/lauric triglycerides, e.g., Captex 350 (Abitec) and caprylic/capric/linoleic triglycerides, e.g., Captex 810 series (Abitec) and Miglyol 818 (Creanova), and in general, include those lipids containing saturated medium and long-chain fatty acids esterified to the same glycerol molecule. A preferred structured lipid is a caprylic/capric/lauric triglyceride, e.g., Captex 350 (Abitec)."

The definition of structured lipids, as described in the present invention (as above), is an accurate and general description of this class of lipids. The definition is in agreement to that which has been published in the literature, i.e., the first line in the article titled "Structured Lipids: An Alternative Energy Source," and on page 91, column 2, lines 14-16 of the article titled

"Metabolic Effects of Structured Triglycerides in Humans." (Exhibits B and C).

The Examiner further stated, "These statements do not represent an absolute requirement for the presence of saturated fatty acids in the glycerol moiety....," however, the definition does require that structured lipids contain BOTH saturated medium and long chain fatty acids esterified to the SAME glycerol molecule. The medium chain component must be saturated. The long chain fatty acid component can be either saturated or unsaturated.

Thus, as stated above, Lacy teaches medium chain triglycerides, but NOT structured lipids. Lacy does not disclose, even in the broadest sense, the general class of lipids known as structured lipids. Thus Lacy does not anticipate the claims and this rejection should be withdrawn.

Discussion of 35 U.S.C. § 103(a) Rejection Over Lacy and Sanchez

The Examiner has rejected claims 1, 3-5, 12, 14-17 and 19-20 under 35 U.S.C. § 103(a). The Examiner stated, "it is deemed obvious to one of ordinary skill in the art to use any triglyceride based on the guidance provided by Lacy with the expectation of obtaining similar results."

An important parameter of the present invention is fibrate solubilization. It is not obvious to one of ordinary skill in the art to use ANY triglyceride with the expectation of obtaining similar results. An example of a fibrate is fenofibrate. The solubility of fenofibrate varies considerably from one triglyceride class to the next (e.g., long chain- vs. structured triglycerides); this is demonstrated in Table 1 below, which lists solubility data for fenofibrate in various triglycerides.

Table 1. Solubility of Fenofibrate in Various Triglycerides

Long chain triglycerides	Solubility (mg/mL)
Super Refined Olive Oil	27.95
Super Refined Peanut Oil	25.60
Super Refined Sesame Oil	33.12
Structured triglycerides	
Caprylic/capric/lauric triglyceride (Captex 350)	66.95
Caprylic/capric/linoleic triglyceride (Miglyol 818)	79.61

Thus, the solubility of fenofibrate in structured lipids is greater than in long chain triglycerides, and it is not obvious to use any triglyceride with the expectation of obtaining similar results.

Sanchez teaches a 10 percent solution of probucol in a medium chain triglyceride.

Probucol is pharmacologically very different than fibrates. Probucol lowers total serum cholesterol levels and has relatively little effect on serum triglycerides (USP DI, 1996, 16th Edition, Drug Information for the Health Care Professional), whereas the general class of fibrates (e.g., fenofibrate) generally lower triglycerides (Tricor, prescription drug labeling, Feb. 1998). Thus, probucol is both chemically and pharmacologically very different than fibrates, and one would not be motivated to use a fibrate instead of probucol with the expectation of obtaining similar results. Attached herewith as Exhibits D and E is professional information regarding probucol and fenofibrate. Thus, this rejection should be withdrawn.

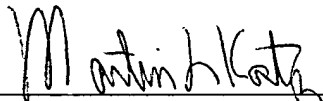
Summary

Favorable consideration and allowance of claims 1, 3-5, 12 and 14-17 is respectfully requested. If any fees are incurred as a result of the filing of this paper, authorization is given to charge Deposit Account Number 23-0785.

Respectfully submitted,

WOOD, PHILLIPS, KATZ, CLARK & MORTIMER

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**Marked-Up Version of Claims**

1. (twice amended) A composition [comprising] consisting essentially of a fibrate dissolved in at least one structured lipid.